

PHARMACY BOARD[657]**Adopted and Filed**

Pursuant to the authority of Iowa Code section 124.201, the Board of Pharmacy hereby amends Chapter 10, “Controlled Substances,” Iowa Administrative Code.

The amendment rescinds current rule 657—10.38(124) and adopts new rule 657—10.38(124) temporarily designating certain identified substances as controlled substances, subject to the applicable security and control requirements and penalties provided for in the Iowa Controlled Substances Act (CSA), and removing one substance from the CSA, in conformance with recent scheduling actions of the federal Drug Enforcement Administration (DEA). The substances affected by this action include three synthetic cannabinoids and acetyl fentanyl, all of which are temporarily placed into Schedule I of the CSA. Synthetic cannabinoids are chemicals synthesized in laboratories and mimic the biological effects of THC, the main psychoactive ingredient in marijuana. These chemicals are much more potent than marijuana and are often marketed as herbal incense or potpourri. They have no accepted medical use in the United States and have been reported to produce adverse health effects, including acute and chronic abuse, addiction, and withdrawal. Acetyl fentanyl, a synthetic opioid, has been linked to at least 39 fatalities nationwide in 2013 and 2014 and poses an imminent hazard to public safety. There is currently no approved medical use for acetyl fentanyl, and it should be appropriately classified as a Schedule I controlled substance.

Also affected by this temporary action is naloxegol, a new molecular entity and derivative of naloxone. The Food and Drug Administration (FDA) recently approved naloxegol for marketing for the treatment of opioid-induced constipation in adults with chronic noncancer pain. Based on the FDA’s approval of naloxegol for marketing for an identified medical purpose and the lack of evidence of a high potential for abuse of this product, the Board concurs with the DEA’s decision to remove naloxegol from control under the CSA.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the December 9, 2015, Iowa Administrative Bulletin as **ARC 2287C**. The Board received no written comments regarding the proposed amendment. The adopted amendment is identical to that published under Notice.

The amendment was approved during the January 13, 2016, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

This amendment is intended to implement Iowa Code section 124.201.

This amendment will become effective on March 23, 2016.

The following amendment is adopted.

Rescind rule 657—10.38(124) and adopt the following **new** rule in lieu thereof:

657—10.38(124) Temporary designation of controlled substances.

10.38(1) Amend Iowa Code subsection 124.204(9) by adding the following new paragraphs “g,” “h,” “i,” and “j”:

g. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: AB-CHMINACA.

h. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: AB-PINACA.

i. [1-(5-fluoropentyl)-1H-indazol-3-yl](naphthalen-1-yl)methanone, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: THJ-2201.

j. N-(1-phenethylpiperidin-4-yl)-N-phenylacetamide, its optical, positional, and geometric isomers, salts, and salts of isomers. Other names: acetyl fentanyl.

10.38(2) Amend Iowa Code subsection 124.206(2), paragraph “a,” introductory paragraph, as follows:

a. Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxegol, naloxone, and naltrexone, and their respective salts, but including the following:

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EDITOR’S NOTE: For replacement pages for IAC, see IAC Supplement 2/17/16.